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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,151

09/20/2005

Richard Melville France

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02/22/2010

PROCOPIO, CORY, HARGREAVES & SAVITCH LLP

530 B STREET

SUITE 2100

SAN DIEGO, CA 92101

EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1657

NOTIFICATION DATE

DELIVERY MODE

02/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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PTONotifications@procopio.com

Office Action Summary	Application No. 10/550,151	Applicant(s) FRANCE ET AL.	
	Examiner David M. Naff	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/3/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An amendment of 10/1/09 amended claims 34-51.

Claims examined on the merits are 34-51, which are all claims in the application.

Claim Objections

5 Claims 34, 37, 38, 46 and 47 are objected to because of the following informalities:

in line 4 of claim 34, --- capable of solidification --- should be inserted after "state" to
provide antecedent basis for solidification in line 9. In line 2 of claim 37, "particulate"
should be replaced with --- particle --- to be consistent with "particle" in line 2 of claim 36.
In line 14 of claim 38, the parenthesis should be replaced with commas to require pectin
10 as a separate member. In line 2 of claim 46, "11" should be replaced with --- 45 --- since
claim 11 has been canceled. In line 4 of claim 47, "specialized cells such as" should be
deleted since all cells recited are specialized. Additionally, in line 5, "or" should be
replaced with a comma.

Appropriate correction is required.

15 ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

20 The specification shall contain a written description of the invention, and of the manner and process of making
and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it
pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode
contemplated by the inventor of carrying out his invention.

25 Claims 34-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with
the written description requirement. The claim(s) contains subject matter which was not
described in the specification in such a way as to reasonably convey to one skilled in the
relevant art that the inventor(s), at the time the application was filed, had possession of the
claimed invention.

The specification fails to contain an adequate description of solidifying a solid in the form of a powder, grain or granule as a first phase. Working conditions have not been provided of how to solidify a solid in the form of a powder, grain or granule.

Response to Arguments

5 The amendment urges that the claims no longer recite the first phase is a gas. The amendment points out the specification discloses the first phase is preferably is not in a liquid or wholly liquefied state, but is rendered sufficiently fluid to mix with and to carry or coat the second phase, and the first and second phases may be in particulate or powder form. However, claim 34 requires the second phase material to be distributed through the material of the first phase, 10 and the composition to be suitable for introduction into a tissue prior to solidification of the first phase material. When the first phase is particles, the working examples describe converting the first phase to a liquid by dissolving the particles in a solvent to form a solution, or melting polymer particles by heating to form a melted tacky semi-solid or liquefied polymer, and then solidifying the solution or melted polymer particles. The specification does not disclose how to 15 solidify a material while in the form of a powder, grain or granule.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

20 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jeong et al (6,841,617) in view of Sheplan et al (6,290,729), and if necessary in further view of Sawhney (6,818,018) or Hubbell (6,129,761).

The claims are drawn to a composition solidifiable to form a porous matrix comprising a first phase material in a fluid state that is selected from a liquid, or a solid in powder, grain or granule form, or a plastic solid such that it is able to flow, and a second phase material distributed through the first phase material. The composition is suitable for introduction into tissue prior to solidification of the first phase material to form the porous matrix.

Jeong et al disclose delivering cells for tissue repair by providing a thermogelling aqueous polymer solution comprising cells at a temperature below the gelling temperature of the polymer, and introducing the solution into a warm blooded animal where the body temperature of the animal is above the gelling temperature to form a gel containing cells that serves as a scaffold for tissue repair (col 7, lines 24-27 and lines 41-49). The polymer solution introduced into the animal has flowability to fill any shape of a defect (col 4, lines 18-27).

Sheplan et al disclose thermoreversible polymer solutions that are liquid at an elevated temperature, but gelled at body temperatures (col 5, lines 10-15). Cells can be added to liquid polymer solution, and the solution forms a gel at a tissue surface where the cells grow and proliferate (col 8, lines 44-46). Composites of increased strength can be formed by incorporation of water insoluble particles (col 7, lines 25-27). Polymer particles can also be incorporated to direct cell growth (col 8, lines 34-35).

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It would have been obvious to add polymer particles to the polymer solution of Jeong et al prior to gelling in an animal to provide in the animal a composite gel having increased strength and which directs cell growth as suggested by Sheplan et al. The polymer solution is inherently a first phase in a fluid state and the particles are inherently a second phase distributed through the first phase. When the polymer solution of Jeong et al contains polymer particles as suggested by Sheplan et al, gelling of the polymer solution in an animal will inherently result in a porous matrix. The mixture of the polymer solution and particles is inherently a composition suitable for introduction into tissue prior to solidification of the first phase polymer solution. Sawhney (col 29, lines 1-29) discloses a hydrogel system containing a thermoreversible polymer for forming a medical implant, and Hubbell discloses providing a cell growth template in an animal by gelling a hydrogel in the animal by temperature change (col 8, line 58, and col 11, line 67). If needed, these references would have further suggested conditions when using a thermoreversible polymer to provide a gel *in situ* in an animal. The conditions of dependent claims would have been matters of choice dependent on individual preference within the skill of the art in view of the disclosures of the references.

Response to Arguments

The amendment urges that Jeong et al contains no disclosure or suggestion for a second phase contained within the gelling liquid. However, Jeong et al is combined with Sheplan et al, and Sheplan et al suggest polymer particles as a second phase to provide the gel with increased strength. Moreover, the claims encompass the second phase being cells added by Jeong et al to the gelling liquid.

The amendment urges that in Jeong et al, there is limit on the molecular weight of a polyester that can be used due to solubility limits, whereas the presently claimed invention does not have this restriction. However, the claims do not exclude a molecular weight disclosed by

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Jeong et al, and the claims encompass using a polyester having the same molecular weight as disclosed by Jeong et al.

5 The amendment urges that the references relate to hydrogels or organogels. However, the claims do not exclude hydrogels and organogels. The claims encompass producing a gel that is the same as suggested by the references.

10 The amendment urges that none of the references disclose or suggest a composition where a second material is distributed through a first material, where the first material can be solidified, in situ in a tissue material to form a porous matrix. However, when adding polymer particles to the gelling solution of Jeong et al as suggested by Sheplan et al, a composition and formation of a porous matrix as claimed will result. Moreover, adding cells as disclosed by Jeong et al will result in a composition and formation of a porous matrix as claimed.

15 The amendment urges that permeability disclosed by Sheplan et al involves pores smaller than macropores. However, the claims do not require pores of a different size than provide the permeability of Sheplan et al. The gels of both Jeong et al and Sheplan et al are a porous matrix that he claims encompass. The claims do not require a different pore structure.

The amendment urges that Sheplan et al form a sealant. However, the claims do not exclude the composition functioning as a sealant after introduction into tissue. In any event, the polymer produced by Sheplan et al can have a use other than as a sealant, and the gel of Jiong et al is not used as a sealant.

20 The amendment urges that gel systems of the references require water. However, the claims do not exclude a gel containing water.

The amendment urges the references do not suggest a tissue scaffold. However, the claims do not require a tissue scaffold. Moreover, the gels of the references are inherently capable of functioning as a tissue scaffold.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS
5 from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the
10 statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

15 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit 1657

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